

Appl. No. 09/692,634
Docket No. 8308
Customer No. 27752

REMARKS

Claim Status

Claims 1, 4-7, 20-22, 26, 27, 54, and 57-60 are pending in the present application. No additional claims fee is believed to be due.

Claims 2-3, 8-19, 23-25, 28-53 and 55-56 are canceled without prejudice.

Claims 1, 4, 54, and 57-60 have been amended. Support for the amendments are found at in the claims as filed.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Rejection Under 35 USC §103(a)

Claims 1-7, 20-27 and 30-37 have been rejected under 35 USC §103(a) as being unpatentable over Deihl (EP0505374B1), in view of Makino et al. (US Patent No. 4789667) and further in view of Kuhrt et al. (Virucidal Activity of Glutaric Acid and Evidence for Dual Mechanism of Action, Antimicrobial Agents and Chemotherapy, Dec. 1984, pp. 924-927). The Examiner states that Deihl discloses a pharmacological composition for the treatment of the common cold by spraying said composition into the oral cavity. The composition comprises vitamin C and a non-toxic zinc salt. The Examiner states that Makino discloses a pharmaceutical composition for external use with enhanced pharmacologically active agent through the skin and that the composition comprises a pharmacologically active agent and an optically active or inactive pyroglutamic acid ester. The Examiner then states that Kuhrt discloses that Rhinovirus as a group is notably sensitive to inactivation in solutions with a pH of less than 5.3. Applicants respectfully traverse this rejection based on the remarks contained herein.

Deihl discloses a composition that provides vitamin C in the manufacture of a pharmacological composition that can be used to treat common colds. Deihl does not teach or suggest a method for treating cold or influenza viruses wherein the method comprises the step of spraying into the nasal turbinates a composition comprising: from about 1% to about 20% pyroglutamic acid and from about 0.01% to about 10% organic acid organic acid having a dissociation constant (pKa) value from about 3.0 to about 5.0; and a pH adjusting agent; wherein the composition is a homogeneous liquid solution having a pH value from about 3.5 to about 5.5 on the nasal tissues. Deihl specifically

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excludes nasal administration by calling out that the invention "is concerned with treatment of the common cold by spraying a pharmacological composition into the oral cavity" See Page 2, lines 24-28. Example V specifies that the compositions are sprayed "every two hours during wakeful periods into the mouths of patients" Additionally, Deihl never teaches or suggest a pH or that the pH of the nasal tissue when the solution is delivered to the nasal tissue is 3.5 to about 5.5 on the nasal tissue or a dissociation constant (pKa) value from about 3.0 to about 5.0. The Examiner relies on the "Dissociation Constants of Organic Acids and Bases, in CRC Handbook of Chemistry and Physics, Internet Version 2007(87th Edition)., to provide support for the inherency of the compounds properties, however, the Examiner cannot rely on this reference, since the current application has a file date of October 19, 2000. Additionally, Deihl never teaches or suggest that the pharmacological composition comprise a pH adjusting agent or pyroglutamic acid.

Makino discloses a pharmaceutical composition for external use that provides for enhanced penetration or permeation of drugs. Makino discloses that pyroglutamic acids can be used to aid in penetration of the drug through the external topical skin or mucosa of a warm blooded animal. Makino fails to teach or suggest a method for treating the cold or influenza viruses wherein the method comprises the step of spraying into the nasal turbinates a composition comprising: from about 1% to about 20% pyroglutamic acid and an from about 0.01% to about 10% organic acid having a dissociation constant (pKa) value from about 3.0 to about 5.0; and a pH adjusting agent; wherein said composition has a pH of less than 4.5; wherein the composition is a homogeneous liquid solution having a pH value from about 3.5 to about 5.5 on the nasal tissues.

The present invention utilizes pyroglutamic acid in combination with organic acids to create a hostile environment on the surface of the nasal cavity not for the delivery of drug that penetrate a mucosa.

Kuhrt discloses a study to determine if the virucidal activity of glutaric acid is solely due to low pH of a solution in which it is tested or to the intrinsic property of the chemical entity. Kuhrt discloses in the summary of the test that glutaric acid appears to inactive RV-14 and several other strains of human rhinovirus by a mode of action independent of acidic pH at low temperatures and that the acidulant effect at room temperature is not detectable. (See page 927, last paragraph). Kuhrt does not teach or

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suggest a method a treating the common cold with a composition that comprises pyroglutamic acid and an organic acid having a dissociation constant (pKa) value from about 3.0 to about 5.0; and a pH adjusting agent; wherein the composition is a homogeneous liquid solution having a pH value from about 3.5 to about 5.5 on the nasal tissues. Kuhrt does not teach or suggest a homogeneous solution that has a pH of 3.5 to about 5.5 on the nasal tissue.

Assuming *arguendo* that one having ordinary skill in the art would combine the disclosures of Deihl, Maniko et al. and Kuhrt et al., one would still fall short of the of Applicants' claimed invention only to arrive at a composition for the mouth that comprises vitamin C, glutaric acid and zinc that utilizes pyroglutamic acid to enhance drug delivery and inactivates RV-14 and several other strains of human rhinovirus by a mode of action independent of acidic pH at low temperatures.

The combination of Deihl, Maniko et al. and Kuhrt et al., do not teach or suggest each and every element of Applicants' presently claimed invention i.e. A method for treating cold or influenza viruses wherein the method comprises the step of spraying into the nasal turbinates a composition comprising: from about 1% to about 20% pyroglutamic acid and an from about 0.01% to about 10% organic acid having a dissociation constant (pKa) value from about 3.0 to about 5.0; and a pH adjusting agent; wherein said composition has a pH of less than 4.5; wherein the composition is a homogeneous liquid solution having a pH value from about 3.5 to about 5.5 on the nasal tissues.

Accordingly, Claims 1, 4-7, 20-22, 26-27, and 31-37 are novel over the prior art of record. Reconsideration and withdrawal of the rejection on this basis are requested.

Conclusion

In light of the remarks and amendments presented herein, Applicants respectfully submit Claims 1, 4-7, 20-22, 26, 27, 54, and 57-60 are allowable over the cited references. Reconsideration and allowance are respectfully requested. In the event that issues remain prior to allowance of the noted claims, then the Examiner is invited to call Applicant's undersigned attorney for further discussion.

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Respectfully Submitted,

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